

2023-2024 COVID-19 Vaccine FAQ

As a reminder: The COVID-19 vaccine is now commercialized. As such, MDHHS is **NOT** involved in the vast majority of the updated COVID vaccine rollout. MDHHS will only receive COVID-19 vaccine allocations for enrolled VFC and Bridge Access (MI-AVP) providers. At this time, the vaccine allocation received by MDHHS is very small and we do not know when another allocation will be received.

Please check back often as this document will be updated as new guidance is received.

What is commercialization?

The U.S. Government ended distribution of COVID-19 vaccine through the current ordering system on September 12, 2023. COVID-19 vaccine commercialization is the transition from COVID-19 vaccine being supplied by the U.S. Government to the vaccine now being supplied by manufacturers for profit. This vaccine is now available through channels like all other ACIP recommended vaccines. It is important to note that with commercialization of COVID-19 vaccines, the State of Michigan will ONLY have federal vaccine allocations for the Vaccines for Children (VFC) program and through the Bridge Access Program to MI-AVP providers.

What is a bridge access provider?

Michigan Bridge Access providers are current MI-AVP providers including local health departments, tribal health organizations, migrant health clinics, and HRSA-supported health centers (Federally Qualified Health Centers- FQHC) to provide COVID-19 vaccines to uninsured and underinsured adults. *Ordering of Bridge COVID-19 vaccine is placed through MI-AVP MCIR E-ordering.*

What is a VFC provider?

Michigan [Vaccines for Children](#) (VFC) providers are enrolled into the program by reaching out to their local health department or MDHHS to provide vaccine to uninsured and underinsured children. A child is eligible for the VFC Program if he or she is younger than 19 years of age and is one of the following: Medicaid-eligible, Uninsured, Underinsured or American Indian or Alaska Native.

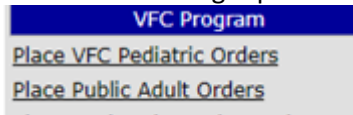
As a VFC provider, am I required to carry COVID-19 vaccine?

All VFC enrolled providers are expected to carry all ACIP recommended immunizations for the population they serve, including the COVID-19 vaccine according to the VFC program requirements acknowledged by signing the VFC provider agreement. Due to the limited number of doses Michigan has on hand, all VFC providers may not be able to order vaccine immediately and should only order the number of doses they expect to use within the next few weeks. MDHHS in collaboration with LHDs, will work alongside the VFC providers as we all navigate this change and what this transition means for each office.

ORDERING

Who can order COVID-19 vaccine through MDHHS?

Michigan MI-AVP/Bridge Access providers and Michigan Vaccines for Children (VFC) providers can order COVID-19 vaccine through MDHHS. Orders for VFC and MI-AVP/Bridge Access COVID-19 vaccines should be placed per normal processes through MCIR e-ordering (see image below). Orders are no longer placed through the MCIR outbreak module.



Where else can I order COVID-19 vaccine?

Providers can order vaccine directly from the manufacture to obtain private COVID-19 vaccine supply, as they do with other ACIP recommended vaccines. Pharmacy providers can also inquire about the Pharmacy component of the bridge access program to obtain vaccine for their uninsured and underinsured adults. Pharmacies interested in joining this program can reach out to [eTrueNorth](#) to learn more.

Is ordering for the 2023-2024 COVID-19 vaccine open for VFC or the MI-AVP Bridge Program?

Ordering is currently open for both VFC and MI-AVP Bridge Access Program providers. We received one allocation to be broken apart among the two programs. Orders must be placed separately through MCIR e-ordering.

Can COVID-19 vaccine orders be placed without submitting monthly documentation?

Currently yes. This will change once the vaccine has become integrated into the program on a more normal basis.

Will MDHHS be involved in receiving and distributing the updated COVID-19 vaccines to providers?

MDHHS will receive allocations of COVID-19 vaccine for uninsured and underinsured adults through the Bridge Access Program. These vaccines will be available to Michigan Adult Vaccine Program (MI-AVP) providers which include: Local Health Departments, Federally Qualified Health Centers, Migrant Health Centers, and Tribal Health Centers. COVID-19 Vaccines will also be available through the [Vaccines for Children program](#).

Does HHS allocate the vaccine quantities for each state?

The vaccine is being allocated to each state by HHS. It is also based on product availability.

After the initial allocation, CDC will conduct weekly monitoring of ordering versus allocations using data from the CDC Allocation Balance to implement replenishment allocations based on awardees' ordering history and the availability of additional doses.

If the 12 years and older presentation through the MI-AVP/Bridge Program is ordered, can it also be given to children 12 -18 years that qualify for VFC?

No, providers must maintain separate inventories for MI-AVP/Bridge and VFC.

How should the VFC and MI-AVP/Bridge stock be separated?

The inventory of VFC and MI-AVP/Bridge vaccine should be kept separate and labeled within the storage unit. Once inventory arrives to your office you will need to set aside in the storage unit the number of 12+ doses ordered for MI-AVP/Bridge and label it accordingly. It will not come to you labeled as MI-AVP Bridge vaccine. This will be the only way to tell the difference between the inventory for the 12 years and older population.

Are VFC providers required to carry all COVID-19 vaccine brand options?

VFC providers do not need to carry every brand (product) option of COVID-19 vaccines. VFC providers must carry at least one vaccine presentation for each population they serve but are not required to carry all the different COVID-19 vaccine products.

Should LHDS approve VFC/MI-AVP COVID vaccine orders?

LHDs should approve COVID-19 orders for existing providers enrolled in the VFC and MI-AVP/Bridge program. Due to limited quantities available, MDHHS is reviewing all orders to ensure maximums are not exceeded and there is sufficient allocation before approving and submitting the order for processing.

When will vaccine arrive?

Please be aware that this time of year there are some delays in receiving regular VFC and MI-AVP/Bridge orders. McKesson prioritizes flu vaccine orders and with the addition of all the COVID orders across the country, they are a bit behind. Frozen vaccines (varicella & MMRV) are shipped directly from Merck, not McKesson, and these orders will come separately from the rest of the VFC vaccine order. Pfizer COVID-19 vaccine is also shipped directly from the manufacture.

If only a partial allotment of the order was received, will the remaining order be backfilled?

If you ordered more than the maximum allowed amount, your order was reduced to the maximum allowable amount due to limited allocations. The order will not be backfilled. A new order will need to be placed once new allocations are received and available.

Did CDC address the conflict between manufactures stating they have plenty of inventory vs lack of allocated public funded vaccine?

Vaccine manufacturers had large supplies but unknown demand. Pfizer and Moderna are working diligently filling orders and getting vaccine out to each state, but it will be a slow rollout.

Will we get Ancillary supplies with the new vaccines?

No, ancillary kits will no longer be offered or supplied, providers are welcome to continue using the stock they have on hand until expiration. If the provider needs supplies to administer the vaccine, they can order supplies as they normally would from their supply vendor.

BORROWING AND WASTAGE**Is borrowing allowed for the Bridge Access program while waiting for private supply to arrive?**

Per CDC guidance, this is not allowed due to limited vaccine through this program.

Is borrowing allowed for the VFC program while waiting for private supply to arrive?

Per CDC Guidance, borrowing of VFC / Bridge (MI-AVP providers) funded COVID vaccine should not be occurring while the supply is limited. Please use these doses on the intended, eligible patients.

What is the wastage procedure for the COVID-19 vaccine?

At this time, VFC and Bridge (MI-AVP) providers will not have to replace spoiled/expired COVID-19 vaccine with private stock vaccine.

Will expired doses be returned to McKesson?

Yes. New guidance from CDC states that the new, 2023-2024 updated formulations of COVID-19 vaccines obtained through the VFC and MI-AVP/Bridge programs SHOULD be returned to McKesson if spoiled/expired, just like other routine vaccines.

Old, COVID-19 deauthorized vaccine cannot be returned to McKesson and should be reported as wastage and disposed of locally, in accordance with local regulations and requirements.

If only 1 dose out of a 3-dose vial is used, what is the protocol?

Borrowing of VFC / Bridge (MI-AVP providers) funded COVID vaccine should not be occurring while the supply is limited. Please use these doses on the intended, eligible patients. The other two unused doses should be wasted.

Are providers supposed to save their partially used vials of vaccine?

VFC vaccine providers do not have to save partially used vials if the vaccine has reached the BUD. If the vaccine has reached the BUD, it should be reported as wastage and disposed of locally, in accordance with local regulations and requirements.

For private vaccine requirements please contact your manufacture.

VACCINE COVERAGE

Will vaccine be provided free of charge for residents that don't have insurance coverage?

Yes, The Bridge Access Program will provide COVID vaccines free of charge to uninsured and underinsured adults, the VFC program will provide vaccines free of charge to VFC eligible children.

Can an administration fee be charged for the COVID-19 vaccine under the VFC program?

Yes, VFC COVID-19 vaccine is treated like other VFC vaccines. Providers may charge a "vaccination administration fee" when vaccinating VFC - eligible children. Administration fees are per vaccine, not per antigen (i.e., as in combination vaccines). The MI VFC administration fee is set at \$23.03 per the Michigan VFC resource book. For further information regarding billing please review the [Michigan VFC resource book](#).

Can an administration fee be charged for the COVID vaccine under the Bridge Access/MI-AVP program?

No. An administration fee cannot be charged for adults who are receiving the COVID-19 vaccine under the Bridge Access/MI-AVP program. MDHHS will reimburse MI-AVP/Bridge Access providers who have administered a Bridge COVID-19 vaccine at a rate of \$39.98/per administration.

Why do Bridge Access/MI-AVP providers get reimbursement for the administration fee from MDHHS and the VFC providers do not?

MDHHS was awarded a supplemental HHS Bridge Program grant to assist with increased reimbursement for Bridge Program COVID-19 vaccine administration. This increased reimbursement is for LHDs, Tribal Health Centers, Migrant Health Centers, and FQHCs who participate in the Bridge Access/MI-AVP program in Michigan, until the end of the program on December 31, 2024.

How will Bridge Access/MI-AVP providers report administrations to MDHHS for reimbursement?

The Bridge Access/MI-AVP providers will run the “doses administered report” within MCIR. The number value on the report should be multiplied by \$39.98/per administration. The dollar amount will be added to the FSR for reimbursement.

- A tip sheet will be provided in the coming days with specific steps on how to pull a report for the number of doses administered.
- In the meantime, please feel free to keep track of the COVID-19 MI-AVP doses administered in your clinic.
- For LHDs: the total dollar amount will be included in the “cost allocation plan/other” line item of the FSR.
- For FQHCs, Tribal Health Clinics, Migrant Clinics: the total dollar amount will be included in the “other expense” line item of the FSR.

Should the vaccine be entered in MCIR?

Yes, vaccine administration should be recorded by dose level eligibility in MCIR. Within MCIR, Bridge providers should pick eligibility code **“MI-AVP”** from the drop down for Bridge vaccine. For VFC vaccine the eligibility code **“VFC”** should be entered.

GENERAL

Can I still vaccinate with the bivalent COVID-19 vaccine?

The Bivalent mRNA (Pfizer-BioNTech or Moderna) COVID-19 vaccines are NO LONGER authorized for use in the United States, they should no longer be administered.

Can I still vaccinate with the original Novavax COVID-19 vaccine?

No. On October 3, 2023, the [Food and Drug Administration \(FDA\)](#) amended the emergency use authorization (EUA) of Novavax COVID-19 Vaccine, Adjuvanted to include the 2023-2024

formula. The Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent) is NO LONGER authorized for use in the United States.

Are jail inmates eligible for COVID-19 vaccine through Bridges stock?

County jails would need to talk to their pharmacy vendor to enroll in the temporary bridge program through [eTrueNorth](#). Normally, with an outbreak situation, the LHDs provide vaccination to inmates in jails. However, there are limited vaccine allocations and funding for the Bridge Program, which runs through December 2024. In addition, because the doses are so limited, we have kept the availability to our current MI-AVP providers. All prisons have been informed by MDOC that they will NOT be receiving doses from the health departments.

Do bivalent doses given after deauthorization need to be invalidated by the LHD?

Currently, no. We are working on the process to ensure the doses are invalidated. We are looking at the process we had in place during the pandemic to have our MDHHS team pull data and reach out for education. The immunization team will share that process when completed.

Is there a way to track the beyond use date (BUD) for COVID-19 vaccine in MCIR?

At this time, we are discussing this with our education and MCIR team to provide some possible guidance on tracking BUD.

If I don't have an ultra-cold freezer what should I do?

In instances where an ultra-cold freezer is not available, Moderna vaccine should be ordered.

Additional instructions for Pfizer shipping container dry ice and data logger returns can be found on the provider commercialization webpage.

Pfizer vaccine will ship in two types of containers: Medium (Reusable) Thermal Shipping Container or Single-Use Thermal Shipping Containers:

If shipped in the Medium (Reusable) Thermal Shipping container: Return BOTH the temperature-monitoring device and thermal shipping container. The office should prepare the box for pick-up from the carrier.

The Single-Use Thermal Shipping Container: Return ONLY the temperature-monitoring device.

Please note: Providers need to take precautions when handling dry ice. Do NOT place dry ice down the drain or flush in the toilet. Do NOT dispose in the trash and do NOT place in a closed area such as airtight container or walk-in cooler.

Dry Ice care instructions: Open the thermal shipping container and leave it at room temperature in a well-ventilated area. This will allow the dry ice to sublime from a solid to a gas. DO NOT handle or touch dry ice with bare hands.

Do I need dry ice or an ultra-low temperature freezer?

It depends. Moderna does not require specialized freezers or dry ice. However, Pfizer doses directly shipping from Pfizer are shipped at ultra-low temperatures (ULT), whereas doses coming from a distributor will be shipped at refrigerated temperatures, so it also depends on where you order from on your private side.

Doses shipped at ultra-low temperatures can be stored: 1) in an ULT freezer, 2) in the original shipping container if dry ice is refilled, or 3) in a regular refrigerator where the vaccine is viable for 10 weeks from the time of defrosting.

Can providers use leftover diluent for the updated Pfizer 6mo-4yrs vaccine administration?

VFC: Diluent will be provided and shipped for VFC orders. Due to vaccine temperature requirements the diluent will be shipped separately. We expect diluent to arrive first, however we have heard of a couple instances where vaccine arrived first, then diluent arrived a couple of days later.

PRIVATE: Yes, leftover diluent can be used. If orders are placed directly through Pfizer, providers should expect the same shipping as VFC vaccine orders. If ordered from a wholesaler, then diluent could arrive in same box because they will be shipping at refrigerated temperatures (2-8 degrees Celsius).

Do we need to use the COVID-19 Vaccine Record Cards?

With commercialization providers are no longer required to use the COVID-19 Vaccine Record Cards. However, if providers wish to continue using them that is acceptable. Per CDC and the State of Michigan there is no policy to dispose of the cards. Providers can follow normal disposal policies associated with their organization, such as shredding or recycling.

Do we need to enter the dose into MCIR within 24 hours?

Vaccine dose reporting in MCIR is no longer required by Federal standards.

Healthcare providers are required to report all immunizations administered to every person born after December 31, 1993, and less than 20 years of age within 72 hours of administration to MCIR. This requirement would include COVID-19 vaccine. MDHHS highly encourages documentation and entry into MCIR for all vaccines administered to any person no matter their age.

Do providers have to report COVID-19 inventory to vaccines.gov?

Providers are required to make their clinics searchable to the public on vaccines.gov. To facilitate this, a new filter has been integrated into the COVID-19 search functionality on vaccines.gov, making it easier for the public to discover provider locations involved in the Bridge Access Program.

Providers who reported their own vaccine inventory on vaccine.org are encouraged to review the steps to establish their Bridge Access Program. This [guidance](#) outlines the steps to establish the Bridge Access Program locations, configure vaccine availability information, and ensure that this data is publicly accessible on vaccine.gov. Providers have the choice to complete these tasks manually or opt for a file upload process, which mirrors the methods previously employed for disclosing COVID-19 vaccine inventory.

Is there an updated Emergency Use Authorization(EUA) Fact Sheet for Healthcare Professionals and Recipients and Caregivers?

The EUA Fact Sheets for Healthcare Professionals and for Recipients and Caregivers have been updated for both [Pfizer](#) and [Moderna](#) for persons 6 months through 11 years.

At this time, there is no EUA Fact Sheet for persons 12 years and older. [Comirnaty](#) and [Spikevax](#) are approved by the FDA and are not under EUA. CDC does not currently have a timeline for availability of a Vaccine Information Statement (VIS) for these COVID-19 vaccines. Until a VIS is available, a provider should use the manufacture's package insert to inform patients about the benefits and risks of that vaccine. Once a VIS is available it should be used. It's important to note that providers should not delay use of a vaccine because of the absence of a VIS.

What date should be used for a VIS publication date until a VIS is received for Comirnaty and Spikevax COVID-19 vaccines?

Until an official COVID-19 VIS is received from CDC, providers should use the date of September 11, 2023, per CDC. In the interim providers should provide the vaccine package insert (PI) to the patient/caregiver. The PI does not need to be printed for each patient. It can be printed, laminated, and shared ahead of time or by using the same [CDC guidance](#) for how to deliver a VIS.